Department of Veterans' Affairs
Harry S. Truman Memorial Veterans' Hospital
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Quality Improvement for Human Research Protection Program

1. **PURPOSE**: To closely monitor compliance with all requirements of the comprehensive Human Research Protection Program at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH).

2. **POLICY**: To conduct an ongoing, continuous Quality Improvement program and to document compliance in the context of the Human Research Protection Program (HRPP) requirements.

3. **RESPONSIBILITIES**: The responsibility for the quality improvement activities for the HRPP are as follows:

a. Hospital Director. The Hospital Director is responsible for the overall assurance of protections for human participants within the HSTMVH.

b. Associate Chief of Staff/R&D (ACOS/R&D). The ACOS/R&D is responsible for the conceptual oversight and administrative leadership with regard to the HRPP.

c. Human Research Compliance Officer (HRCO). The HRCO is responsible for the day-to-day monitoring of the HRPP, including the ongoing Quality Improvement activities.

d. Administrative Officer/R&D (AO/R&D). The AO/R&D is responsible for the organizational support and deployment of resources as are required to maintain compliance with HRPP activities, including Quality Improvement audits.

4. **PROCEDURES FOR AUDITS**: The audit procedures for the HRPP are as follows:

a. Audits of Project Files. The HRCO will audit a minimum of five (5) human research project files per quarter to ensure completeness of records, including original applications, IRB documentation, investigator communications, and synchronization with computerized tracking systems (PROMISE, Research Compliance Management System [RCMS], and PRISM). Specifically, the audit will ensure that accurate and complete records are maintained as follows: (1) date of original IRB approval, (2) date of original R&D Committee approval, (3) date of most recent IRB approval, and (4) date by which next IRB continuing review must occur.

b. Audits of VA Training Records. The VA databases (e.g.TEMPO) which document the training required for human researchers ("Overview of Good Clinical Practices" and "HIPAA Privacy Training") will be audited by the HRCO for training compliance; an audit of the training records for five (5)human research staff members will be conducted on a quarterly basis.

c. Audit of IRB Training Records. The IRB training website will be audited by the HRCO for compliance with required biannual IRB web-based training; an audit of the training records for five (5) human research staff members will be conducted on a quarterly basis.

d. Audit of IRB Continuing Review Report Compliance. The IRB website will be audited by the HRCO to ensure that all human research protocols operating within the HSTMVH are compliant with IRB continuing review reports; a minimum of five (5) randomly selected projects will be audited on a quarterly basis.

e. Audit of Informed Consent Documentation. The placement of consent documents within the medical records of human research participants at the HSTMVH will be audited by the HRCO; a minimum of five (5) medical records of human participants will be audited on a quarterly basis.

f. Audit of Investigator Records and Practices. Human research investigators at the HSTMVH will receive personal visits by the HRCO to ensure adequacy of records security, data management, operational procedures, consent documentation, reporting of adverse events, adequacy of consent forms, compliance with inclusion/exclusion criteria, and management of deviations from protocol. A minimum of five (5) human research investigators will be visited (audited) personally on a quarterly basis.

5. **PROCEDURES FOR RESPONDING TO ALLEGATIONS OF NON-COMPLIANCE WITH HRPP REQUIREMENTS**: In addition to retrospective audits of compliance with the HRPP, any allegation of noncompliance which arises will receive responsive examination as follows:

a. All complaints or allegations of non-compliance pertaining to the HRPP will receive a prompt response.

b. All complaints and allegations of non-compliance pertaining to the HRPP will receive thorough investigation by the HRCO.

c. Appropriate remedial actions and consequences for non-compliance with either HRPP or IRB requirements will be pursued, including termination of protocols, restrictions on privileges to conduct research, and/or potential disciplinary actions.

d. Any complaint or allegation regarding non-compliance with HRPP and/or IRB policies will be promptly reported to the HRCO, who in turn will be responsible for providing immediate notification to both the ACOS/R&D, the Hospital Director, and the R&D Committee.

e. In any situation where non-compliance with HRPP or IRB requirements is confirmed, immediate remedial action(s) will be taken (and documented), and prompt disclosure will be made to the VA Office of Research Oversight (ORO) and/or other appropriate agencies.

6. **ASSURANCE OF APPROPRIATE OVERSIGHT OF IRB**: A key component of the Quality Improvement procedure for the HRPP is careful oversight of IRB activities. Specific oversight is accomplished as follows:

a. The HRCO maintains electronic access to IRB data pertaining to VA-related projects.

b. A VA representative attends a minimum of 75% of IRB meetings in order to monitor appropriate review and oversight of VA-related projects.

c. A representative of the affiliated IRB attends a minimum of 75% of VA R&D meetings.

d. The minutes of all IRB meetings are presented for review at R&D meetings.

e. The HRCO monitors specific IRB activities as follows: (a) qualifications and experience of new IRB chairpersons, (b) appropriateness of IRB membership and experience in the context of research under review, (c) participation of representatives and/or advocates for vulnerable populations, and (d) adequacy of IRB policies and procedures, and (e) appropriate monitoring of adverse events.

f. Quarterly meetings are held between VA and IRB officials (convened by HRCO) in order to maximize communication, collaboration, and compliance with all HRPP requirements.

7. **AUDIT AND MONITORING DOCUMENTATION**: On a quarterly basis, the HRCO will provide a written summary of audit and monitoring activities to the Research & Development (R&D) Committee. Results of audit activities pertaining to the HRPP will be maintained on file for a minimum of seven (7) years.

8. **MONITORING CHANGES IN HRPP POLICIES AND REGULATIONS**: Officials responsible for the HRPP will closely monitor all policies and regulations which pertain to HRPP requirements. Strategies for effective monitoring will be as follows:

a. The HRCO and other officials, as appropriate, will participate in recurring training in order to remain cognizant of all relevant HRPP policies and regulations.

b. Communications from the VA Office of Research and Development, the VA Office of Research Oversight (ORO), and the VA Center on Advice and Compliance Help (COACH) will be closely monitored in order to maintain a keen awareness of HRPP policies and regulations.

APPROVED:

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Director